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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): contagious bovine pleuropneumonia

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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): contagious bovine pleuropneumonia

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Abstract

Contagious bovine pleuropneumonia has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of contagious bovine pleuropneumonia to be listed, Article 9 for the categorisation of contagious bovine pleuropneumonia according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to contagious bovine pleuropneumonia. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, contagious bovine pleuropneumonia can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The animal species to be listed for contagious bovine pleuropneumonia according to Article 8(3) criteria are species of the family Bovidae as susceptible.

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Keywords: contagious bovine pleuropneumonia, CBPP, *Mycoplasma mycoides* subsp. *mycoides*, Mmm, Animal Health Law, listing, categorisation, impact

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on contagious bovine pleuropneumonia (CBPP) according to the criteria of the AHL articles as follows:

- Article 7: contagious bovine pleuropneumonia profile and impacts;
- Article 5: eligibility of contagious bovine pleuropneumonia to be listed;
- Article 9: categorisation of contagious bovine pleuropneumonia according to disease prevention and control rules as in Annex IV;
- Article 8: list of animal species related to contagious bovine pleuropneumonia.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of CBPP according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see Section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

Contagious bovine pleuropneumonia is an infectious and contagious respiratory disease affecting Bovidae (bovines, yaks and water buffaloes) and caused by a wall-less bacteria (Mollicute): *Mycoplasma mycoides* subsp. *mycoides* (Mmm). It is characterised by a unilateral acute inflammation in the lung and pleural cavity of susceptible animals leading to large quantities of infective droplets being excreted when the animals are coughing. In the chronic stage lesions consist of necrotic lung tissue encapsulated by a fibrous tissue, called a sequestrum. Animals with those chronic lesions may still harbour Mmm and cause the long term persistence and possible shedding of Mmm.

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

No naturally susceptible wild species are identified. Although slightly positive complement fixation tests (CFT) have been recorded from wildebeest and hippopotami (Shifrine and Domermuth, 1967), subcutaneous inoculation of live *Mycoplasma* did not induce any typical lesion as compared to control bovines inoculated in parallel, so these species are not likely natural hosts despite these findings. Positive complement fixation tests have been detected only in camels (Paling et al., 1988) but no mycoplasmas were isolated from nasal secretions from camels or buffaloes, which is similar to findings in American camelids (Hung et al., 1991). While CFT was performed with a crude antigen, it is highly probable that the positives were in fact cross-reactors with other mycoplasmas or bacteria.

Parameter 2 – Naturally susceptible domestic species (or family/orders)

The following species are susceptible to disease: cattle (*Bos taurus*), yak (*Bos gruniensis*) (Xin et al., 2012), and water buffalo (*Bubalus bubalis*) (Santini et al., 1992). Susceptibility has been deemed lower in water buffalo compared to cattle, while water buffaloes in contact with Mmm-infected cattle presented typical lesions from which Mmm could be re-isolated (Provost, 1988).

The following small ruminant species have been identified as susceptible to infection, based on exceptional isolations of Mmm: goats in Nigeria (Perreau, 1971); sheep and goats in Portugal (Brandao, 1995) and goats in India (Srivastava et al., 2000).

Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

African buffalo (*Syncerus cafer*) (Shifrine et al., 1970) has been experimentally infected with subcutaneous inoculation of Mmm sometimes leading to re-isolation of Mmm, 53 days after inoculation, although no gross lesions were observed.

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Furthermore, among domestic species, sheep and goats have been experimentally infected in France (Dujardin-Beaumetz, 1906), and goats in Cameroon (Yaya et al., 2000), inducing peritonitis after intra-abdominal inoculation.

Rabbits have been used to grow Mmm for vaccine development and showed some degree of susceptibility after multiple passages in China (Xin et al., 2012).

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

There is no natural wildlife reservoir known so far.

Parameter 6 – Domestic reservoir species (or family/orders)

So far no domestic reservoir species has been identified. However, CBPP outbreaks have occurred in Europe at regular intervals (1956; 1967; 1982–1999) without detection of cases in-between the outbreaks. Molecular studies have shown that these outbreaks were caused by Mmm strains of European origin (Dupuy et al., 2012). Hence, Mmm strains must have stayed hidden in an unidentified carrier host e.g. small ruminants not showing symptoms or cattle harbouring low-pathogenic strains before reversion to virulence or other, although the source remained unclear.

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/incidence

For CBPP, it is important to differentiate the clinical appearance (presence of symptoms) from the presence of infection defined as isolation of Mmm. OIE defines a CBPP case based on the presence of Mmm. The most recent outbreaks in Europe occurred in mostly in Portugal (from 1982 to 1999) and in Italy (from 1990 to 1995) (Regalla et al., 1996). In Portugal, the seroprevalence measured by CFT was never high with a peak at about 1.2% in 1987 and a progressive decline as control measures were implemented. As CFT is not specific, positive CFT sera had to be confirmed using western blotting at the end of the eradication campaign when the prevalence was close to zero. The regions where the prevalence was high corresponded to higher animal and farm densities as well as common milking parlours. In Italy, half of the outbreaks were concentrated in three areas. In these areas, the yearly herd incidence was about 1,340/100,000, while in the rest of Italy, it amounted to 2/100,000 (Regalla et al., 1996).

In Africa, the disease is endemic and the local situation depends largely on the control measures that are implemented. In Ethiopia in the Borena region, 62% of bull batches had at least one seropositive animal (hence was considered positive), but the individual seroprevalence was very low: 0.4% (Alemayehu et al., 2015). In Mali, a national survey conducted in 2011 on 199 herds totalling about 8000 sera showed that a very high number of herds had to be considered infected (85%) while the individual prevalence reached 18%. In northern Cameroon, Wade et al. (2015) found a very high proportion of lung suspicious lesions (30%) but isolation or polymerase chain reaction (PCR)-positive results were obtained only from 1.6% to 3.4%, respectively.

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

The clinical prevalence can be quite low, even in the face of an acute outbreak. A good example of this fact can be found in a paper from Bygrave that describes the occurrence of a CBPP outbreak at Archers post in Kenya in 1966 (Bygrave et al., 1968). The decision to slaughter the herd allowed the study of 2,541 carcasses. During this outbreak, acute clinical signs were limited to less than 50% of the cattle involved in the epizootic while 90% were infected. The majority of cattle with acute lesions on necropsy showed typical clinical signs for only about 3 days prior to death. Most cases classed as 'chronic' on necropsy had little or no clinical respiratory embarrassment prior to slaughter. The typical 'soft cough' of CBPP cattle was not a marked feature; only 25% of animals with acute lesions at necropsy had this symptom when forced to move. Similar findings were seen in experimental 'in-contact' infections with control animals (Hudson and Turner, 1963). Out of 90 in-contact animals, 57% showed symptoms but more than 75% had typical lesions.

Mortality

Parameter 3 – Case-fatality rate

Reported case-fatality rates observed in the control groups of experimental CBPP reproductions are highly variable, from 0% to 70%:

Hudson and Turner (1963): 0%, 17%, 18% and 28% in the control groups of four successive experiments

Gilbert et al. (1970): 0% and 22% in two experiments

Davies et al. (1968): 0%

Hudson (1968a): 18% and 36% in two experiments

Doutre et al. (1972): 73%

Yaya et al. (1999): 50%

These data are obtained from experimental studies, where the conditions were controlled. There were no antibiotic treatments installed and therefore the mortality observed truly reflects what happened in those experiments. The variability of the observed percentage can be attributed to many factors:

- The virulence of Mmm strains may vary (although we have no precise information yet on the exact molecular basis of virulence).
- There is some breed variation of susceptibility (Hudson, 1968b).
- There are obviously a number of predisposing factors that may influence the outcome of the infection. CBPP being characterised by an acute inflammatory process, every event that modulates the immune system (co-infections with viruses, parasitic infestation, etc.) may have an impact on CBPP outcome.

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

CBPP is not zoonotic.

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

All mycoplasmas are naturally resistant to penicillins (absence of a cell wall). Mmm can easily become resistant to aminoglycosides (based on the creation of a streptomycin resistant variant of the T1/44 vaccine strain obtained after five passages). The mutation rate conferring resistance to streptomycin, spectinomycin, novobiocin, erythromycin and tylosin was estimated at $10^{-7,5}$ to $10^{-8,3}$ (Lee et al., 1987). There is no actual data on the antimicrobial resistance in Mmm strains circulating in Africa. However, a parallel can be made with *Mycoplasma bovis*, which is present in Europe and for which a retrospective study has been performed over a period of 30 years (from 1980 to 2010) in France (Gautier-Bouchardon et al., 2014). The antimicrobial resistance became:

- substantial for tylosin, tilmicosin, tulathromycin and spectinomycin;
- moderate for enrofloxacin, danofloxacin, marbofloxacin and oxytetracycline;
- no differences were observed for gamithromycin, tildipirosin, florfenicol and valnemulin.

Nevertheless, in the European Union (EU), animals are not treated against Mmm infection, therefore there would not be any significant additional danger to animal health as a consequence of possible development of drug resistance.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

The infectious period can be subdivided in the latent phase where no clinical signs are detected and then the clinical phase (see Parameter 2 below). The clinical stage of the disease can itself be divided in two stages, the acute and the chronic stage. This was the basis for the development of compartment models (Lesnoff et al., 2002).

Animals in the acute stage (i.e. animals with evolving pleuropneumonia lesions, which are not encapsulated) are highly infectious, because of the expectoration of infective droplets. The mean duration for this phase can be estimated as approximately 1 month (excluding the latent phase), although it is clear this duration can vary considerably from one case to another.

Animals in the chronic stage of the disease present lesions called sequestra, which are encapsulated. Mmm can be isolated from these lesions for up to 12 months (Windsor and Masiga, 1977a). The real infectious risk presented by these animals is unknown, but is certainly limited (in the Lesnoff model, a relative risk of less than 1/50 compared to animals in the acute stage was considered) (Lesnoff et al., 2002, 2004a).

In natural infections under normal conditions, the infectiousness of the animals may be modulated by the antibiotic treatments.

Parameter 2 – Presence and duration of latent infection period

There is experimental evidence that Mmm can be detected in the upper respiratory tract from 26 to 40 days before these animals show any symptom (Hudson and Turner, 1963) and this period can last at least 3 months, as seen with animals that were contaminated by the 'in-contact' method (through exposure of naïve animals to animals infected following exposure through intubation) without showing any overt disease signs (Belli et al., 1989).

Parameter 3 – Presence and duration of the pathogen in healthy carriers

Animals with sequestra may be in a long-term carrier state, which may last up to 1 year (Windsor and Masiga, 1977a). However, this is based on a single experiment where it was difficult to determine, when the animal was originally contaminated. A period of 1 year after the last case is required to declare a zone as 'free' according to the OIE.

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

Mmm is theoretically very fragile as it does not have any cell wall. However, it has a polysaccharidic pseudocapsule, which may help resist harsh conditions especially through the formation of biofilms (McAuliffe et al., 2008).

Temperature has an effect only when it is higher than 43°C and UV light has a deleterious effect on Mmm (loss of three logs in 7 min and 9 logs in 37 min) (Hudson, 1968c). This means that in Europe, temperature will not be responsible for Mmm inactivation but exposure to sunlight may.

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

The main route of transmission is by direct contact between an infective animal (either presymptomatic or in the acute phase of the disease) and a naïve one. The transmission occurs through infected droplets released during coughing. This mode of natural transmission explains the lung localisation of the lesions of CBPP although artificial inoculations through other routes may lead to inflammatory lesions in other organs (Willems reaction after subcutaneous inoculations, peritonitis, myositis, etc.).

Animals in the chronic stage of the disease may still harbour Mmm, but their real infectivity is unknown. *Mycoplasma* shedding might be intermittent and at low level. These animals may be responsible for the long-term persistence of CBPP and prolonged risk.

There is a single publication relating the presence of Mmm in the urine of infected cattle which may account for indirect transmissions (Masiga et al., 1972). Transmission to naïve cattle through artificially contaminated hay was successful (Windsor and Masiga, 1977b), but it involved Mmm concentrations that are unrelated to field reality. Previous studies to infect naïve animals with contaminated premises failed (Hudson, 1972).

Long-distance contaminations with droplets that are transported by the winds have been suspected in Italy (Giovannini et al., 2000). In Lombardy, in 1990–1993, there was a spatial segregation of CBPP non-infected and infected herds, in the absence of direct contacts, which is in clear favour of an indirect transmission of CBPP. In fact, the long-distance transport of droplets that are contaminated by mycoplasmas has already been proven for *Mycoplasma hyopneumoniae* over 5–10 km (Otake et al., 2010).

Vertical transmission of CBPP has not been recorded. Fetuses can be infected by Mmm although they do not present lesions (Windsor et al., 1972) but this usually results in abortions. In an experimental infection, an in-contact infected cow gave birth to a calf, which died rapidly with a polyarthritis and from which Mmm could be isolated (Belli et al., 1989).

Mmm has been isolated from the sperm of infected cattle in Italy (Stradaioli et al., 1999) but also with sheath washing in Portugal (Gonçalves, 1994). This is in accordance with the normal occurrence of mycoplasmas in epithelia tissues where they can scavenge metabolites they are unable to synthesise and where they find a protective environment (37°C in a humid atmosphere). There seems to be no reports with evidence of CBPP sexual transmission.

The presence of Mmm in ticks collected from CBPP cases was described in Angola (Mendes, 1959). Such finding was confirmed later on in Kenya and it was shown that the ticks contained about 10^3 log Mmm per tick. However, experimental transmission through infected ticks failed.

To summarise, the routes of transmission based on their importance are as follows:

- Direct contact is the main source of contamination/transmission (airborne)
- Distant spread may be responsible for some cases of transmission (airborne)
- Vectors are not considered to play any role in the transmission of CBPP
- Fomites are not considered to play any role in the transmission of CBPP
- Animal products do not play any role in the transmission of CBPP
- Environmental contamination is considered negligible due to the fragility of mycoplasmas.

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

This is not applicable.

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

Reported transmission rates range from 0.07 to 0.13 (Mariner et al., 2006) and 0.03 per week (Lesnoff et al., 2002).

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

There are very few publications on R_0 evaluation for CBPP. Accurate estimation is complicated by the fact that this value can vary a lot according to variation in Mmm strain virulence, breed susceptibility, and other unknown predisposing factors.

Determination of transmission rates (beta) and calculation of R_0 were done (Balenghien et al., 2004, 2005). Using an epidemiological SEIR model for the spread of CBPP combined with the dynamic of seroconversion to describe serological diagnostic data from an experimental vaccine trial, it was found that the transmission contact rates for subclinical, clinical and chronic infective states are respectively, $0.084/N$, 0.45 and $0.14/N$ per animal per day, where N is the herd population size, and the basic reproductive number corresponding to this trial ($N = 28$) is $R_0 = 27$ (Balenghien et al., 2005). In different conditions, the expression of R_0 is given by, $R_0 = \beta_0 (29 + 14N)$ where β_0 (ranging between 0.01 and 0.45) is the transmission rate of clinical infected animals (Balenghien et al., 2004).

R_0 was estimated at 1.24–2 in an agropastoral husbandry system in West Ethiopia (Lesnoff et al., 2004b). The model that was used to estimate this parameter was validated through follow-up of more than 1,600 animals over a period of 2 years. Another estimate of R_0 achieved with another model and serological results obtained in southern Sudan (Mariner et al., 2006) ranged from 3.2 to 4.

The discrepancy between the two evaluations can have multiple origins. The husbandry type differs a lot, the serological tests used were different (CFT for Mariner et al. (2006) and competitive enzyme-linked immunosorbent assay (cELISA) for Lesnoff et al. (2004b)) and the models also varied. In fact Mariner's evaluation may be biased as the sero-positivity with the CFT test does not correlate with prevalence rate but more to the incidence of CBPP during the past three months (CFT detecting mostly short-lived IgMs).

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in the EU

Today (2017), there are no CBPP cases reported in the EU, while the last case was recorded in Portugal in 1999.

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

Sporadic cases of CBPP have been reported in Europe with 10–20 years interval, i.e. 1935; 1956; 1967; 1982–1996. These are considered resurgences and not due to importation (Dupuy et al., 2012). This was demonstrated by a 'haplotype' network analysis showing that all the Mmm strains of European origin derived from a single ancestor and were positioned in an individual branch completely independent from the other Mmm strains of African origin. The most recent Mmm strains of European origin (posterior to 1980) differed from the ancestor and the Mmm strain isolated in 1967, at the French-Spanish border, by a large DNA deletion.

Risk of introduction

Parameter 3 – Routes of possible introduction

The possible routes of introduction to the Union include import of live animals, semen and embryos from infected countries.

Parameter 4 – Number of animal moving and/or shipment size

The import of cattle into the EU from CBPP-infected countries or zone is prohibited.

Parameter 5 – Duration of infectious period in animal and/or commodity

The infectious period is considered to be maximum 1 year in a chronic carrier. See Section 3.1.1.5 Parameters 2 and 3.

Parameter 6 – List of control measures at border (testing, quarantine, etc.)

The most important control measures at borders include ban on the import of live cattle or water buffaloes or yak from infected countries or zones. Testing is not a feasible, as there is no accurate test that could detect all subclinical infected animals and quarantine should be very long.

Parameter 7 – Presence and duration of latent infection and/or carrier status

No precise data are available.

Latent carriers can shed Mmm for up to 3 months without showing any overt sign of disease. However, active shedders showing symptoms will become positive in serology (CFT first and then cELISA). Seropositivity does not last very long and chronic carriers may survive and become seronegative. CFT detected antibodies (IgMs mostly) will wane sooner than cELISA detected antibodies.

Parameter 8 – Risk of introduction

The risk of introduction is affected by

- Importation of live susceptible animals from supposedly free countries which do not have an efficient surveillance system in place.

This risk is considered extremely unlikely as the importation of live cattle into the EU is strictly regulated and controlled (meat products are not a CBPP risk), especially for cattle originating from sub-Saharan Africa where CBPP exists today. There could be an indirect risk if cattle (or embryos, see below) from infected countries are imported into other non-EU countries where surveillance is not optimal and where CBPP remains undetected or unreported.

- Importation of contaminated semen or embryos which may be used in naïve cows and which may give birth to contaminated calf.

This risk is also considered extremely unlikely. However, it should be considered especially if there are some programs for the conservation of endangered indigenous African cattle breeds.

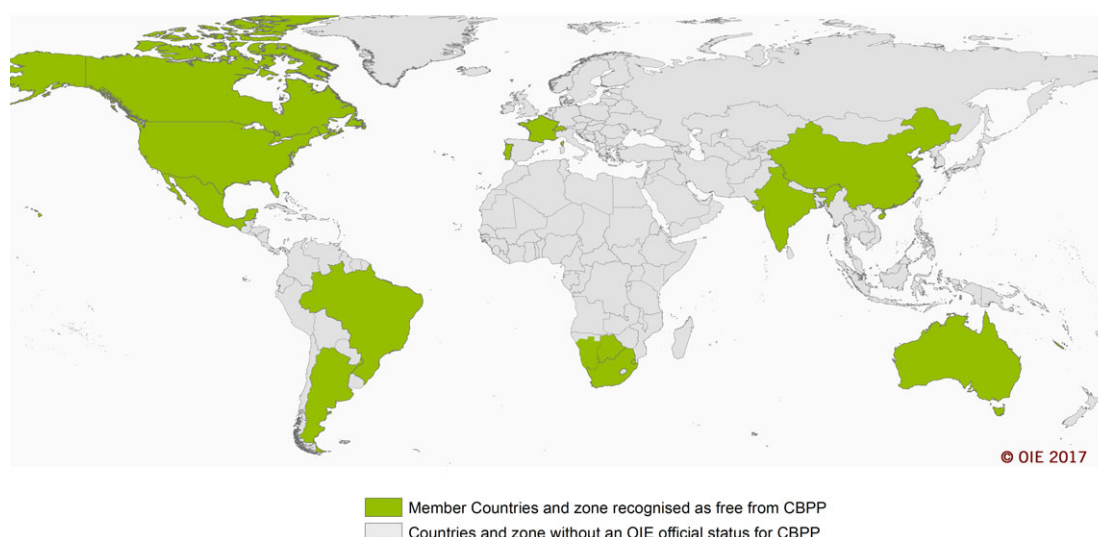
- Resurgence of Mmm strains that may have escaped detection by the classical surveillance system. Such strains may circulate unnoticed in the form of low virulent strains that could circulate in susceptible animals as they will not induce any lesion nor any seroconversion. Or these strains could circulate in non-susceptible species, such as small ruminants and then contaminate cattle on rare occasions. Such possibility exists as Mmm was isolated from small ruminants in India (Srivastava et al., 2000) while no outbreak was detected or notified in cattle at this time.

This risk can be considered as extremely unlikely or very unlikely at the most. However, it cannot be disregarded as such events have occurred in the past with CBPP resurgence in Europe at 10–20 years interval (Dupuy et al., 2012). The only way to mitigate this risk would be to perform regular testing of *Mycoplasma* strains isolated from cattle but also from small ruminants in the countries/regions that were affected during the last CBPP outbreaks (Portugal, Spain and Italy). This procedure may not be considered compulsory to obtain a CBPP-free status as CBPP surveillance is usually performed at the slaughterhouse with meat inspection detecting suspicious CBPP lesions. However, isolation of mycoplasmas is the only way to spot low pathogenicity strains.

In 2016, only few countries were declared officially free of CBPP by the OIE (Figure 1).

OIE Member Countries' official CBPP status map

Last update May 2017



CBPP freedom according to the OIE means absence of *Mycoplasma mycoides* subsp. *mycoides* and not simply the absence of disease.

Source: OIE

Figure 1: Recognised countries free of CBPP by the OIE

In Europe, only Switzerland, Portugal and France applied and were granted that status.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

Direct detection of Mmm

- Isolation of Mmm is quite easy if the laboratory has some experience in *Mycoplasma* isolation and that the quality of the sample is adequate (no bacterial contamination, no antibiotic residue). Mmm can grow in 24–48 h. Pleural fluid from acute cases can contain up to 109.5 mycoplasmas per ml. For example, isolation of *Mycoplasma* strains circulating in ruminants is one of the surveillance tool put in place in France through the 'Vigimyc' network. *Mycoplasma* isolated in regional labs are sent to a reference laboratory (ANSES Lyon) where their identity will be verified to rule out the possibility of Mmm strains circulating unapparent in the herds (Chazel et al., 2010). To our knowledge, such comprehensive network for *Mycoplasma* identification does not exist in other MS.
- Specific PCR and quantitative PCR (Q-PCR) have been developed. The OIE Manual of Standards mentions those of Bashiruddin et al. (1994), Dedieu et al. (1994) and Miserez et al. (1997), and for Q-PCR (Gorton et al., 2005; Fitzmaurice et al., 2008; Lorenzon et al., 2008; Vilei and Frey, 2010; Schnee et al., 2011).
- Some isothermal loop-mediated amplification systems (Mair et al., 2013) have been developed but have yet to be validated in the field.
- There is a PCR that can detect specifically the T1 vaccine strains (Lorenzon et al., 2000).
- Once isolated, Mmm strains can exquisitely be characterised at the genome level, for example by an 'extended MLSA' system involving 53 genes (Dupuy et al., 2012). Since then, the sequencing technology has been improved a lot (for example the PacBio NGS). Today de-novo whole genome sequencing will still be difficult because of large DNA duplications in the Mmm genome but comparison with a reference can easily be performed.

Indirect detection

There are two prescribed serological tests: the CFT and the cELISA.

- The CFT was developed as early as 1930 in Japan (Yamagiwa et al., 1930) and was popularised in Australia by Campbell and Turner (1936). The CFT played a major role for the detection of infected animals during the eradication of CBPP in Australia which was based on the repetitive test-and-slaughter plus vaccination strategy (Newton, 1992; Turner, 2011). It also played a major role in Europe during the last outbreaks in 1967 (at the French-Spanish border), in 1982 (again at the French-Spanish border) and in 1993 (Portugal and Italy) for the slaughter of positive herds.

The CFT is not strictly specific (97–99%) and false-positive results are to be expected when large enquiries are performed, for example in Switzerland (Stärk et al., 1995). When CBPP prevalence is very low or zero, CFT-positive samples can usually be confirmed using the western-blotting technique.

There are few CFT kit producers in Europe. CIRAD was still producing and selling such kits but may not do so anymore because of the small and erratic demand. Stocks of antigen are nevertheless still kept in case of an emergency situation (this antigen is very stable).

- A specific competitive ELISA has been developed (Le Goff and Thiaucourt, 1998). Its specificity lies in the use of a monoclonal antibody. Its specificity is higher than 99.5% when the test is performed under quality procedures. It is difficult to determine its sensitivity. It is lower than the CFT at an early stage after infection (as CFT detects mostly immunoglobulins M (IgMs)) but it is higher at a later stage, notably to detect chronic cases (Amanfu et al., 2000; Muuka et al., 2011; Tardy et al., 2011; Séry et al., 2015).

This test is produced by IDEXX ref: P05410-10 and all batches are controlled by CIRAD before release.

It is important to note that CFT and cELISA are both considered herd tests. They will not be able to detect latent Mmm shedders, which do not display circulating antibodies and they will have a low sensitivity for the detection of chronic carriers (*Mycoplasma*-induced antibodies are short-lived). A practical consequence is that serological results should be expressed in 'herd prevalence' with sampling frames including the random selection of herds in the various compartments but a targeted selection of animals in the chosen herds to increase the sensitivity of the results.

- Western-blotting can be used as a confirmatory test to rule out false positivity, notably by the CFT (Gonçalves et al., 1998) and especially at the end of an eradication programme when the predictive value of CFT positive results is very low.

Control tools

Parameter 2 – Existence of control tools

There are four control measures for CBPP: slaughter, control of movement, antibiotic treatments and vaccination.

A strategy for the control/eradication of CBPP will inevitably be a combination of these control measures that must be applied either at individual or herd level or in a timely spatiotemporal way.

Slaughter and control of animal movement will not be discussed as they are not specific for CBPP.

Antibiotic treatments

Although they are banned when CBPP is diagnosed, there are great chances that these antibiotic treatments will be put in place by veterinarians in the face of respiratory signs in cattle herds before any precise diagnostic is obtained. There are great chances that CBPP signs will be confused with other bacterial infections such as pasteurellosis or *Mycoplasma bovis* infections.

These antibiotic treatments may be quite effective and they will lead to a lack of detection and possible unnoticed expansion of the disease unless some specific lesions are discovered after slaughter. Unfortunately, autopsies are not regularly performed for cattle that have died and the bodies are very often disposed of directly.

Vaccines

Vaccines have been developed as soon as the infective nature of CBPP was proven. The first 'vaccines' were in fact inoculation procedures that mimicked the inoculation procedures for small-pox.

In Africa, these inoculations were performed at the bridge of the nose (Blancou, 1996) while in Europe it was performed at the tip of the tail (Willems, 1852).

Live vaccines have been obtained by empirical attenuation after a number of passages *in vitro* or *in ovo*. The most well-known vaccine strains are the V5 developed in Australia (Hudson, 1968c), inoculated at the tip of the tail, which played a major role in the reduction of CBPP prevalence before stamping out procedures were put in place to achieve eradication. The KH3J that was obtained in southern Sudan (Juba) (Hudson, 1965) and the most popular one, T1/44, developed in East Africa by Sheriff and Piercy (Sheriff and Piercy, 1952; Piercy, 1958) after 44 passages in embryonated eggs. A streptomycin resistant derivative of T1/44, T1sr, was obtained some time later that could be introduced together with the rinderpest vaccine (Provost, 1969).

The main drawback of these vaccines is that some of them have a residual virulence (V5, T1/44) which would make them unacceptable by today's standards in Europe. Another drawback is the short duration of immunity they induce (6 months for T1sr and 1 year for T1/44) which did not allow the eradication of CBPP (Thiaucourt et al., 2000) while the combined campaigns achieved eradication of rinderpest, notably in Africa.

However, they have the great advantage that they do not induce the production of long-lasting seroconversion, allowing the detection of affected herds by the CFT or cELISA provided the sampling is performed at least 3 months after vaccination.

Numerous new types of vaccines are in the process of development but very few have been validated so far due to a lack of funding and interest by donor agencies. At CIRAD, an inactivated vaccine based on a modified Mmm strain, which is deleted for an immunogenic antigen, and therefore, a DIVA vaccine, has been developed. It received a preliminary experimental validation during the 'VACNADA' project financed by the EU (project ended in 2011).

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

None.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

The impact in the EU if introduced is not known. Such information is impossible to predict as there are too many variables at stake.

In Africa, CBPP was re-introduced in Tanzania in 1994. It rapidly spread to the whole country in spite of vaccination efforts aiming at preventing the spread of the disease to the South. The direct losses due to cattle mortality, vaccination campaigns and surveillance were estimated at more than 11 million dollars (Msami et al., 2001) for a cattle population of 10 million. The vaccination campaigns that were performed at that time did not succeed in preventing the spread and CBPP is now prevalent in the whole country. Losses are less conspicuous as the disease evolves in an enzootic manner.

Botswana, which faced the same reoccurrence of CBPP, decided to adopt a strict stamping out policy in the CBPP affected zone (320,000 heads slaughtered) with an estimated cost of 100 million dollars.

In other parts of Africa, where CBPP occurs in an enzootic form, the annual losses due to that disease in 12 countries were estimated at about EUR 45 million (Tambi et al., 2006).

These figures are certainly not transposable to Europe.

The potential impact is likely from the cost of the eradication campaigns and restrictions to trade rather than the direct costs.

In the best of scenarios, the surveillance systems, which are based on the passive surveillance of lung lesions observed at slaughterhouses, are very efficient in all Member States and new CBPP outbreaks will be detected very rapidly before the disease has time to spread. In that case, the cost will be strictly limited to the few herds that will have to be slaughtered.

This is theoretically feasible. Lesions of CBPP are quite conspicuous (unilateral pleuropneumonia with profuse exudate or sequestra), serological tests are available for confirmation and cultivation of Mmm is quite easy with a number of European laboratories that are able to cultivate and identify them.

However, this is not likely to happen. It is quite probable that CBPP outbreaks will not be spotted immediately and animals will be given antibiotic treatments masking the symptoms. Animals that die may not be inspected and go directly for disposal. The efficiency of the surveillance system mostly relies on the detection of suspicious lesions at the slaughterhouses (OIE accepted strategy as more than 95% of animals are slaughtered in such slaughterhouses). However, the technicians may not be sensitised to the CBPP risk as the EU did not experience any outbreak since 1999. It is not known if all EU veterinary services organise training sessions that include observation of CBPP lesions.

The final cost will therefore depend on:

- the extension of the disease before it is spotted;
- the swiftness of response and the control measures implemented.

In France, there is a national survey of *Mycoplasma* strains isolated in ruminants to possibly detect the presence of Mmm (Vigimyc network coordinated by ANSES) even in the absence of suspicions.

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

CBPP is not a zoonosis.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

CBPP is very painful due to the pleurisy in the acute stage and then due to the fibrous tissue connecting the costal and lung pleura once the lesions have healed. In Africa, chronic carriers are called 'lungers' and usually lag behind the rest of the herd during movements. Therefore, there may be an important impact on welfare, although this would not relate to a large number of animals, since the within-herd prevalence of infection is usually low.

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

CBPP does not affect wildlife.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

CBPP does not affect wildlife and Mmm does not persist in the environment.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

An introduction of CBPP into the EU may have huge consequences for intra-Community trade and EU exports, thus having the potential to generate at least a commercial crisis.

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

Not listed in the CFSPH for potential bioterrorism and agroterrorism agents (CFSPH, 2016).

The disease is present in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2017 (OIE, 2014).

Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

Although CBPP is listed in the list of human and animal pathogens and toxins for export control from the Australia Group, it is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.

Parameter 3 – Included in any other list of potential bio-agroterrorism agents

It is not listed.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

The cELISA is produced by IDEXX ref: P05410-10.

Kits are produced under ISO 9001, all kit batches are quality controlled externally by CIRAD which performs the test under ISO 17025 accreditation by COFRAC.

International proficiency testing is organised regularly by CIRAD.

For the CFT, the availability of kits is more questionable. However, such kits were produced in the past in Europe during the last outbreaks in 1982–1996 and there is no doubt that these kits could be produced again.

The cELISA may be more reliable because of its specificity and facility for quality monitoring.

Isolation and PCR can also be performed under accreditation although there is no kit available so far (because of the absence of a market).

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

The accuracy of the cELISA at individual level: specificity is near 100% when the test is performed under quality management, while the sensitivity varies by disease stage and time of sampling after the onset of outbreak. It can be 60–70% for up to 6 months and much lower after 1 year.

This is the reason why the epidemiological unit to be considered should be the herd.

The accuracy of the cELISA at herd level: specificity remains near 100% when the test is performed under quality management (considering a true-positive sample reaching a value above the cut-off plus the uncertainty of measurement). Sensitivity is much higher when targeting animals in the herd, which have suffered from suspicious signs during the past 12 months, hence improving the sensitivity of detection, although a specific estimate of the herd sensitivity is available.

Feasibility

Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

Blood can be used for testing.

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

In Europe, no vaccine is authorised for sale.

Live vaccines are available in Africa. Two strains are available, T1/44 which was developed in 1952 (Sheriff and Piercy, 1952) by attenuating the original strain with 44 passages in embryonated eggs.

This strain has been empirically attenuated; hence, it is not known which genetic modifications induced its attenuation nor which genes (and gene expression) are necessary for inducing protection. In fact a 'good CBPP' vaccine is a compromise between attenuation, which allows using them as a vaccine that does not induce inflammation at the site of inoculation, and keeping a minimum of virulence to trigger an immune response in the vaccinated animals.

This strain has a certain residual virulence and may induce a local swelling at the site of injection when naïve animals are vaccinated for the first time. The percentage of reacting animals is very variable and may reach exceptionally up to 17% (in Zambia in 1971) (Revell, 1973). Local reactions do not occur after re-vaccinations. A streptomycin resistant variant of T1/44, called T1sr, has been developed later on to permit the development of a combined vaccine protecting against rinderpest and CBPP (Provost, 1969). T1sr is void of any residual virulence.

The minimum dose for these vaccines is 10⁷ viable organisms but higher doses (10⁸) are recommended by the OIE to take into account the probable loss of titres along the chain between the production plant and the vaccinated cattle.

The protective immune response is considered cell-mediated and there is no strict correlation between the level of antibodies that can be detected in an animal and its immune status (protected vs susceptible).

NB: CIRAD has been developing another type of CBPP vaccine based on the use of a modified pathogenic strain (one gene coding for an immunogenic protein has been deleted and the antibiotic resistance gene has also been deleted subsequently). The final product is killed antigen which is formulated into an oil-emulsion as an adjuvant. Therefore, it is a DIVA vaccine as antibody rise after vaccination can be followed with the cELISA. Detection of infected animals could be performed by using the deleted antigen. However, the companion serological test is not developed yet.

This vaccine has passed a preliminary validation process in Mali within the framework of the VACNADA project (funded by the EU: VACNADA, online).

However, CIRAD could not obtain any grant to finish the validation of this product which is therefore remaining as a 'potential vaccine' not available on the market.

Parameter 2 – Availability/production capacity (per year)

Availability for the live vaccines such as T1/44 is there as the master seed is kept at CIRAD and producing batches require only classical means (fermenters and freeze driers).

There are about seven vaccine producers located in Africa. At least one of them is located in a CBPP-free country (the Botswana Veterinary Institute) and in the future MCI in Morocco may be in a position to produce such vaccines under Good manufacturing practices (GMP).

There are about 40–50 million doses of CBPP vaccines that are produced in Africa annually. This is far less than the number of susceptible cattle population in the affected countries (more than 350 million).

Effectiveness

Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

The protection afforded by a single injection is sometimes limited (70% protection at the herd level); however, this level increases after subsequent re-vaccinations and vaccinated herds are considered completely protected. This is the reason why CBPP vaccination campaigns in Africa should target 100% of the susceptible population and plan vaccination activities over successive years.

In fact, the protection rate may be higher but it is difficult to evaluate in experiments that always include a limited number of animals with a lot of factors that are not completely controlled (virulence of the challenging strain notably).

The vaccination failures that are sometimes reported in Africa are usually resulting from an improper implementation of the vaccination campaigns. The absence of consistent serological markers

after vaccination does not allow a seromonitoring of the vaccination campaigns efficacy. This is a real problem for the follow-up of the vaccination campaigns in Africa.

Parameter 4 – Duration of protection

The duration of protection using T1sr is 6 months, while it is 1 year using T1/44.

Feasibility

Parameter 5 – Way of administration

Vaccine administration is subcutaneous.

3.1.4.3. Article 7(d)(iii) Medical treatments

Availability

Parameter 1 – Types of drugs available on the market

Usually forbidden for CBPP, but the following antibiotics may be used: long acting tetracyclines, macrolides such as gamithromycin or fluoroquinolones.

Parameter 2 – Availability/production capacity (per year)

This is not applicable.

Effectiveness

Parameter 3 – Therapeutic effects on the field (effectiveness)

Although being effective in curing symptoms, antibiotics may not be able to prevent the persistence of Mmm in treated animals. This was one of the reasons for prohibiting their use for CBPP in the framework of an eradication of the disease. However, antibiotic treatments will certainly reduce dramatically the excretion and should be considered in strategies combining vaccination to protect susceptible animals and antibiotic treatments to reduce shedding and contamination risk.

Feasibility

Parameter 4 – Way of administration

Depending on the antimicrobial used, some products are injected intramuscularly while others are injected subcutaneously.

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Availability

Parameter 1 – Available biosecurity measures

Prohibiting import of live animals from infected countries is the primary biosecurity measure to reduce the risk of introduction. The detection of CBPP suspicious cases into a shipment of animals to be imported into a CBPP-free zone such as the EU should be followed by a strict quarantine until CBPP is confirmed. In that case, the immediate slaughter of the shipment should be implemented.

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

The ban of import of live cattle from infected zones has effectively protected Europe from CBPP since time immemorial (the 1990 outbreaks were due to resurgence of the disease and not from an importation).

The destruction of infected herds effectively removes the Mmm shedder animals and cut the contamination routes.

Hence, the effectiveness of the whole campaign will depend on the ability to detect all positive herds. The combination of two serological tests such as the CFT and cELISA should enhance the sensitivity of serological testing at herd level. Besides, these two tests can be performed under quality assurance which should ensure more reliable results.

An extreme example is Botswana, where it was decided to slaughter the whole cattle population in the contaminated zone (300,000 heads) to get rid of CBPP and regain a freedom status allowing exports to Europe. The strategy was very efficient. No CBPP outbreaks were detected after repopulation with cattle from CBPP-free countries (notably South Africa) (Masupu et al., 1997).

*Feasibility*Parameter 3 – Feasibility of biosecurity measures

The feasibility of biosecurity measures including import and movement restrictions depend on the efficacy of surveillance systems in place in the various countries.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products*Availability*Parameter 1 – Available movement restriction measures

As CBPP is mostly transmitted by direct contact between an infected animal and a susceptible one, the restriction of movement of live animal will certainly prevent a further spread of the infected zone. The key parameter is therefore to define an infected zone that includes all infected farms. This may be difficult because CBPP incubation period is quite long. Many animals may have been moved away during this period before CBPP is definitely confirmed.

*Effectiveness*Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

Not completely fool-proofed as long distance contamination has to be considered. However, once a CBPP outbreak has been identified, it has to be expected that sick animals (which are the real Mmm shedders) will be detected and eliminated rapidly, hence reducing dramatically the distance contamination risk.

*Feasibility*Parameter 3 – Feasibility of restriction of animal movement

The feasibility of restriction of animal movement depends primarily on the existence of laws pertaining to the management of crisis situations when CBPP (or any other regulated disease) appears.

Each MS should have a contingency plan ready for such occurrence. This is requested by the OIE when countries are applying for an official freedom status.

These plans can benefit from a booklet prepared by the FAO in 2002 (Geering and Amanfu, 2002).

3.1.4.6. Article 7(d)(vi) Killing of animals*Availability*Parameter 1 – Available methods for killing animals

Animals can be brought to slaughterhouses provided they are transported in sealed trucks (but this may be against animal welfare rules). Such a procedure was implemented by Australia. Animals from the infected zone were transported by train, and not by hoof, to slaughterhouses.

*Effectiveness*Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

The killing of animals is very effective. Different strategies have been used worldwide.

In Australia, the initial strategy, at farm level, involved the slaughter of all CFT-positive animals (mobile laboratories were available) and the vaccination of the others. This procedure was repeated every three months as vaccination antibodies disappear quite rapidly. At the end of the eradication campaign, when herd prevalence was drastically reduced, vaccination was stopped and replaced by a strict herd stamping out policy (Newton, 1992).

In Europe, they slaughter targeted positive herds and vaccination has never been allowed (Regalla et al., 1996).

In Botswana, the slaughter involved the whole cattle population in the infected zone and was indeed effective as described above (Masupu et al., 1997).

Feasibility

Parameter 3 – Feasibility of killing animals

As stated in Parameter 2 above, this slaughter policy has already been implemented with success in Europe and it allowed Portugal and Italy to regain their freedom status after some years. This is naturally costly but what is sure is that without any coordinated strategy CBPP would gradually spread to the whole of Europe.

What really matters is to have a reliable surveillance system in place that allows the detection of CBPP outbreaks very rapidly. A swift response, based on the slaughter of infected herds is the most likely to be successful and with the best cost/benefit result.

If the detection of CBPP is performed at a later stage, then naturally the cost of a slaughter policy may be too high (both financially and socially). Various strategies may then be discussed.

This strategy will involve the four classical measures: slaughter, restriction of animal movement, treatment and vaccination.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Availability

Parameter 1 – Available disposal option

As indirect contamination through fomites is negligible and CBPP is not a zoonotic risk, carcasses can be used for human consumption.

Effectiveness

Parameter 2 – Effectiveness of disposal option

Carcasses do not present any risk and can be manipulated in any abattoir.

Feasibility

Parameter 3 – Feasibility of disposal option

No specific precaution is needed when manipulating carcasses. CBPP is not a zoonosis and there are usually no farms at the vicinity of slaughterhouses which minimise the risk of any aerosol transmission.

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

If CBPP was to be identified in a MS, the first action to be implemented would be to define an 'infected zone' (IZ) and a 'surveillance zone' (SZ) around it.

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

CBPP control is not an option right now in the EU as treatments or vaccination alone cannot lead to an eradication of the disease and would not allow the contaminated EU MS to regain their CBPP-freedom status.

This policy could be eventually modified if an inactivated DIVA vaccine was available. Such vaccines could be used in the IZ to prevent CBPP spread and to restrict culling to infected herds. The drawback of such a policy is that export of cattle may be prohibited from that zone until vaccination is stopped and sufficient time is allowed to be sure that Mmm does not circulate in that zone. However, products like meat or milk could be exported safely.

Parameter 2 – Cost of eradication (culling, compensation)

For the time being, there are only two culling strategies that can be implemented in the EU. Both are based on the culling of herds and not individuals as for CBPP the epidemiological unit that makes sense is the herd.

- Culling the whole herd population in the IZ. This would be the safest policy if the IZ is restricted in size (i.e. if the surveillance network has been sufficiently efficient to detect CBPP cases very rapidly). The cost of this strategy is easily calculated (mean cost of cattle in the zone multiplied by the total number of animals in the infected zone). These costs do not take into account indirect costs which may be linked to the loss of valuable genetic material for example.

- Culling infected herds while monitoring the status of the other herds.

The cost would then be equal to the culling costs added to monitoring costs. Culling costs will depend primarily on the percentage of herds which are found positive. Multiple cycles of monitoring and culling will have to be implemented, roughly at 3 months interval (time needed to allow animals in the incubation period to show symptoms and to be detected either by clinical surveillance or by serology).

The cost of monitoring in the IZ will also depend on the chosen strategy (all animals tested in the herd or targeted sampling of animals that are either old or that showed suspicious symptoms in the past months). The safest strategy would be to test all sampled sera with the two prescribed tests, the CFT and the cELISA, as it would increase the sensitivity of detection at the herd level. Herds in which there are only few positives by the CFT should be confirmed by western blotting to reduce the number of negative herds to be culled (a likely issue at the end of the eradication process).

The estimated serological testing cost at the laboratory may vary from EUR 5–15 per test on top of which the sampling has to be added (this cost may vary a lot from country to country but estimates have already been issued for other diseases as sampling is not disease specific).

Parameter 3 – Cost of surveillance and monitoring

These costs will also depend on the strategy that is implemented in the SZ. There is no consensus on the size of the SZ (10 km around the IZ?). This may naturally be modified after an epidemiological enquiry is performed and a mapping of animal movements to and from the IZ is obtained.

- Syndromic surveillance has to be implemented in that zone as to report any respiratory signs that could be linked to CBPP. In that case, serology will have to be implemented in the suspected herd. In case of positivity the IZ and SZ will have to be modified accordingly.
- Serological testing could also be implemented in the SZ but maybe not on all herds.

Parameter 4 – Trade loss (bans, embargos, sanctions) by animal product

It is likely that all exports of live animals from the infected country will be banned, unless the said country can prove that only a zone (according to the OIE definition) is affected. The trade loss will then be depending on the importance of export of live animals from that zone.

Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

As CBPP is not present in the EU, this importance cannot be estimated so far.

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

The social acceptance of the slaughter strategy is difficult to predict. It will mostly depend on the extent of the CBPP infected zone and the number of herds which will have to be culled. Owners may be reluctant to accept slaughter as antibiotic treatments may be used and that vaccines are available (both of which are forbidden by the regulations).

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

There is theoretically no welfare issue as humane slaughtering will be implemented.

Parameter 2 – Wildlife depopulation as control measure

There is no welfare issue for wildlife as these species do not play any role in the epidemiology of CBPP and will not be impacted by the control measures.

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Control measures may have an impact on the environment only if antibiotics are included in the control strategy. This is not the case now in most European countries which ban antibiotic treatments for CBPP.

Biodiversity

Parameter 2 – Mortality in wild species

Wildlife species are not known to be affected.

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about CBPP (Table 1). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 1: Outcome of the expert judgement on the Article 5 criteria for contagious bovine pleuropneumonia

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		Final outcome
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	N
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	NC
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Table 2). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

Table 2: Outcome of the expert judgement related to criterion 5 B(iv)

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
B(iv) The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	NC	25	75	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes:

- CBPP may have huge consequences and generate a crisis for intra-community trade and EU exports, if introduced in EU.

Supporting No:

- It is not listed as a bioterrorism or agroterrorism agent.

3.2.2. Outcome of the assessment of contagious bovine pleuropneumonia according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 1, CBPP complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about CBPP (Tables 3, 4, 5, 6 and 7). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 3: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for contagious bovine pleuropneumonia

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present only in a very limited part of the territory of the Union	Y
2.1	The disease is highly transmissible	N
2.2	There are possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N

5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

Table 4: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for contagious bovine pleuropneumonia

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	N
2.1	The disease is moderately to highly transmissible	Y
2.2	There are possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	NC
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = non-consensus (NC).

Table 5: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for contagious bovine pleuropneumonia

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character	N
2.1	The disease is moderately to highly transmissible	Y
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N

5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No).

Table 6: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for contagious bovine pleuropneumonia

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of Sections 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

Table 7: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for contagious bovine pleuropneumonia

Diseases in category E need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL and/or the following:		Final outcome
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 8 and 9). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

Table 8: Outcome of the expert judgement related to criterion 2.4 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
2.4 (cat. B) The disease may result in high morbidity with in general low mortality	NC	25	75	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes:

- Mortality can be variable. It is usually low, but could be high according to the virulence of the strain of Mmm and to the susceptibility of the host breed. Morbidity ranges from 5% to 68%.

Supporting No:

- Both morbidity and mortality can have high levels, and in untreated animals mortality can be up to 70%.

Table 9: Outcome of the expert judgement related to criterion 4 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
4 (cat. A, B) The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC	50	50	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes:

- If introduced and spread uncontrolled, there could be a significant impact on the economy.
- As there is no treatment, there could be high morbidity and mortality. The yearly herd-incidence in Italy was 1.34% in the 1990s.

Supporting No:

- The individual seroprevalence appears to be normally low, not a large number of animals is clinically affected; thus, it would be more a welfare issue for the affected animals.

3.3.2. Outcome of the assessment of criteria in Annex IV for contagious bovine pleuropneumonia for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 3–7. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'.

A description of the outcome of the assessment of criteria in Annex IV for CBPP for the purpose of categorisation as in Article 9 of the AHL is presented in Table 10.

Table 10: Outcome of the assessment of criteria in Annex IV for contagious bovine pleuropneumonia for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	Y	N	Y	Y	Y	N	NC	N	Y	N	N
B	N	Y	Y	Y	NC	N	NC	N	Y	N	N
C	N	Y	Y	Y	N	N	N	N	Y	N	N
D						Y					
E						Y					

According to the assessment here performed, CBPP complies with the following criteria of the Sections 1–5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment CBPP complies with criteria 1, 2.2, 2.3 and 2.4, but not with criterion 2.1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and CBPP complies with criterion 5b, but not with criteria 3, 5a, 5c and 5d and the assessment is inconclusive on compliance with criterion 4.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment CBPP complies with criteria 2.1, 2.2 and 2.3, but not with criterion 1 and the assessment is inconclusive on compliance with criterion 2.4. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and CBPP complies with criterion 5b, but not with criteria 3, 5a, 5c and 5d and the assessment is inconclusive on compliance with criterion 4.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment CBPP complies with criteria 2.1, 2.2 and 2.3, but not with criteria 1 and 2.4. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and CBPP complies only with criterion 5b.
- 4) To be assigned to category D, a disease needs to comply with criteria of Sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4, with which CBPP complies.
- 5) To be assigned to category E, a disease needs to comply with criteria of Sections 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, with which CBPP complies.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about CBPP. The Article 8(3) criteria are about animal species to be listed, as it reads below: '3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.¹ According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for contagious bovine pleuropneumonia according to the criteria of Article 8(3) of the AHL are as displayed in Table 11.

Table 11: Main animal species to be listed for contagious bovine pleuropneumonia according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/Species
Susceptible	Mammalia	Artiodactyla	Bovidae	Cattle (<i>Bos taurus</i>), yak (<i>Bos grunniensis</i>), water buffalo (<i>Bubalus bubalis</i>), goat (<i>Capra hircus</i>), sheep (<i>Ovis aries</i>), African buffalo (<i>Sincerus cafer</i>)
		Lagomorpha	Leporidae	not specified
Reservoir	Not identified			
Vectors	None			

¹ A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors, the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

4. Conclusions

TOR 1: for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

- According to the assessment here performed, CBPP complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

TOR 2a: for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

- According to the assessment here performed, CBPP meets the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL.

TOR 2b: for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

- According to the assessment here performed, the animal species that can be considered to be listed for CBPP according to Article 8(3) of the AHL are species of the family Bovidae as susceptible, as reported in Table 11 in Section 3.4 of the present document.

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Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
CBPP	contagious bovine pleuropneumonia
cELISA	competitive enzyme-linked immunosorbent assay
CFT	complement fixation tests
GMP	Good manufacturing practices
ICBA	Individual and Collective Behavioural Aggregation
Ig	immunoglobulin
IZ	infected zone
Mmm	<i>Mycoplasma mycoides</i> subsp. <i>mycoides</i>
MS	Member State
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
SZ	surveillance zone
ToR	Terms of Reference

Annex A – Mapped fact-sheet used in the individual judgement on contagious bovine pleuropneumonia

Annex A can be found in the online version of this output ('Supporting information' section):
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